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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,894	08/04/2003	Yung-Feng Nien	ASI 128	2895

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EXAMINER

KOSSON, ROSANNE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/632,894

Applicant(s)

NIEN ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. These make the claims difficult to understand. For example, claim 1, step (d) recites "after cutting the tissue profile of the cellular sample, said controlling circuit output a signal to drive said working platform. Claim 1, step (e) recites "applying an impact force to impact said biological tissue slide thereby drop down said captured cell sample."

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, step d, recites the limitation "the impact lever linking head." There is insufficient antecedent basis for this limitation in the claim. Claim 1, step c, recites cutting (*sic*) a minute profile of a cell sample. The term "minute" is not defined in the specification and is, therefore, indefinite, rendering the metes and bounds of the claim unclear. Claim 2 recites a tissue sample protecting means comprising a "thin" sheet with a hole "just equal" to the diameter of a sampling mortar. The terms "thin" and "just equal" are not defined in the specification and are, therefore, indefinite, rendering the metes and bounds of the claim unclear. Thin is an adjective of

relative degree- how thin is the sheet, compared to what? If the tissue sampling hole is just equal to the sampling mortar in diameter, what is the difference between equal and just equal? By how much is the diameter of the hole larger or smaller than the diameter of the mortar?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al. (WO 99/39176). Goldstein discloses a device for capturing biological tissue samples produced by laser capture microdissection (LCM). The device comprises a contactless cutting apparatus for cutting biological tissues with a laser beam focused to a point (42, 46), a microfeeding mechanism that drives a working platform (38, 40- the stage holding slide 32) on which the tissue samples (34) are supported, an impact lever and linking head providing a downward force (62) that pushes a tissue sample through a hole and into a collection vessel (66). The tissue samples are covered and held above the collection vessels with a thin, flat protecting means (18). The device also includes a clear slide for holding the tissue samples (32) (see Figures 1 and 11; p.7, lines 30-35; p. 10, lines 20-25; p. 13, lines 13-26). Thus, a holding of anticipation is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. (WO 99/39176). As discussed above, Goldstein discloses a device for capturing biological tissue samples produced by laser capture microdissection. The device comprises a contactless cutting apparatus for cutting biological tissues with a laser beam focused to a point (42, 46), a microfeeding mechanism that drives a working platform (38, 40- the stage holding slide 32) on which the tissue samples (34) are supported, an impact lever and linking head providing a downward force (62) that pushes a tissue sample through a hole and into a collection vessel (66), a thin, flat protecting means (18) for covering tissue samples and holding them above the

collection vessels, and a clear slide for holding the tissue samples (32) (see Figures 1 and 11; p.7, lines 30-35; p. 10, lines 20-25; p. 13, lines 13-26).

The reference also discloses a method for capturing biological tissue samples using the device. The method comprises labeling a profile of a sample to be captured, controlling a drive means to drive a working platform for capturing the sample, and cutting it with a contactless cutting means (see Abstract and p. 1, line 24, to p. 2, line 5). The method also comprises driving the working platform to position the sample below an impact lever linking head and impact lever. The impact lever and impact lever linking head apply a downward force to pass the sample through a hole and into a collection vessel (see Figures 1 and 11; p.7, lines 30-35; and p. 13, lines 13-26). The reference does not disclose placing the tissue sample on a biological slide, inverting the slide and fixing the slide on a working platform. Nevertheless, in the reference, as in Applicants' invention, the tissue sample is located on a slide affixed to a working platform (compare Applicants' Figure 1 to Figure 1 in Goldstein) before it is labeled and cut. But, preparing an LCM tissue sample attached to a slide is routine in the pertinent art, and the manner of preparing such slides is clearly a result-effective parameter routinely optimized by the artisan of ordinary skill at the time of Applicants' invention. The preparation of slides for performing the method of the instant invention, as recited in claim 1, clearly would have been a matter of routine optimization on the part of the artisan of ordinary skill and therefore obvious under § 103(a). Therefore, a holding of obviousness is required.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. (WO 99/39176) in view of Dorian et al. (U.S. 5,521,079). As discussed above, Goldstein discloses a device for capturing biological tissue samples that comprises a contactless cutting apparatus for cutting biological tissues with a laser beam focused to a point (42, 46), a microfeeding mechanism that drives a working platform (38, 40- the stage holding slide 32) on which the tissue samples (34) are supported, an impact lever and linking head providing a downward force (62) that pushes a tissue sample through a hole and into a collection vessel (66), a thin, flat protecting means (18) for covering tissue samples and holding them above the collection vessels, and a clear slide for holding the tissue samples (32) (see Figures 1 and 11; p.7, lines 30-35; p. 10, lines 20-25; p. 13, lines 13-26). This device anticipates Applicants' claimed device in which tissue samples are prepared by LCM. Also, as discussed above, Goldstein discloses a method for using this device to capture tissue samples into collection vessels which renders obvious Applicants' claimed method for capturing tissue samples where the samples are prepared by LCM. Goldstein does not disclose contactless cutting of biological tissue with an air knife. Dorian discloses contactless cutting of biological tissue with an air knife to prepare microencapsulated tissue samples (see Figures 1 and 2; column 1, lines 12-33; column 4, line 19, to column 5, line 14; and Examples 1-4 in columns 7 and 8). The advantages of microencapsulation are that the cells continue to receive nutrients and metabolize normally, while remaining protected from microbial contaminants or components of the immune system from the host from which the cells are derived. In this

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microencapsulation process, both larger microcapsules containing cells or tissue and smaller microcapsules containing no biological material (blanks) are produced (see column 6, line 64, to column 7, line 13). One of ordinary skill in the art at the time that the invention was made would have recognized that the microcapsules produced by the method of Dorian, or using the air knife of Dorian, would have to be sorted or separated to obtain tissue-containing microcapsule samples for further use or study. The skilled artisan would also have recognized that the device and method as disclosed in Goldstein is designed to transfer user-selected tissue samples to collection vessels for further use. One of ordinary skill in the art would reasonably have expected that the tissue samples produced by the method of Dorian would have been transferred to slides for sample separation and collection using the device and method of Goldstein. Thus, the artisan of ordinary skill would have been motivated to have combined the Goldstein device for capturing biological tissues with the air knife method of preparing tissue samples as disclosed in Dorian for the advantages disclosed in Dorian. Thus, a holding of obviousness is required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-5:00.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner  
Art Unit 1651

  
**IRENE MARX**  
**PRIMARY EXAMINER**

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